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EXAMINER

HAND, MELANIE JO

ART UNIT	PAPER NUMBER
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3761

NOTIFICATION DATE	DELIVERY MODE
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ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/663,226	Applicant(s) BOEHRINGER ET AL.	
	Examiner MELANIE J. HAND	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28,30-33 and 35-42 is/are pending in the application.
- 4a) Of the above claim(s) 1-22,28,30-33,35-38 and 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-27,39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 23-28 and 39 have been considered but are moot in view of the new ground(s) of rejection prompted by applicant's amendment to the claims. However examiner will address the essence of applicant's arguments herein. As to the argument that the cylindrical piece of fabric disclosed by Svedman is not inherently anisotropic, applicant is referred to the first paragraph on page 8 of applicant's specification. In the cited paragraph, applicant discloses that the spirally wound, cylindrically configured winding shown in Fig. 3, preferably made of gauze, is responsible for the anisotropic nature of the wound packing. None of these limitations, spirally wound, cylindrically configured winding or gauze are recited in claim 23. Svedman discloses a cylindrical piece of fabric or foam. Regardless of how that cylindrical piece is formed or whether it is a roll, when the suction is applied to the cylinder of foam or fabric material, any contractible cylinder of material, contraction will occur in both dimensions of the cylinder but the contraction is and will always be, greater in the direction perpendicular to flow of suction because, in the direction parallel to flow, the area over which the suction force extends is greater than in the direction perpendicular. Thus, the same suction force distributed over the smaller area perpendicular to flow will exert a greater pull or contraction per unit area. Such a universally occurring and universally understood property of foam or fabric materials such as those disclosed by Svedman does not need to be explicitly taught in a reference. Svedman anticipates all of the claim limitations and teaches a contractible material with unequal dimensions, thus Svedman necessarily anticipates the anisotropic wound packing recited in claim 23.

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2. As to the argument that Svedman does not anticipate the limitation of a wound packing being inherently more contractible in said first direction than said second direction, first, amending claim 23 to recite that the wound packing is inherently more contractible in a first direction than a second does not overcome the rejection because, again, foam is inherently more contractible in one direction than another upon application of contracting force. This limitation of an inherently contractible wound packing material constitutes new matter for reasons stated below in the "Claim Rejections - 35 U.S.C. 112" section of this Office action as it is reciting a material that, regardless of its composition or dimensions, is more contractible in a first direction than a second direction. Further, the first direction of contraction of the foam or fabric pad of Svedman will necessarily extend along the at least one axis of the wound parallel to the skin adjacent the wound because Svedman discloses that the pad may take up more or less of the space in the wound cavity. ('494, Col. 2, lines 60, 61) When it takes up more of the space, oriented either vertically or horizontally, the first direction of contraction will necessarily extend along said at least one axis of the wound, because whether the pad is oriented vertically in the wound or horizontally, one of the directions of contraction upon application of suction has to be the first direction of contraction as claimed and that direction will necessarily extend generally parallel to the skin surface, i.e. along said at least one axis of the wound.

Specification

3. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: there is antecedent basis for the following: (1) a wound packing inherently more contractible in one direction than another, (2) a first direction of contraction, (3) a second

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direction of contraction, all recited in claim 23 as amended, and (4) a first direction of wound packing, recited in claim 39 as amended.

Claim Objections

4. Claim 25 is objected to because of the following informalities: the phrase “said radial axis” appears to contain a typographical error, since the claim also recites radial axes.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 23-28 and 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. With regard to independent claims 23 and 39, there is no support in the disclosure as originally filed for a wound packing that is inherently more contractible in a first direction than a second direction. The word “inherently” does not appear anywhere in the disclosure, and therefore, there is no disclosure as to its meaning. The amendment implies that “inherently contractible” means something other than contractible only upon application of suction, and there is no support for this.

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7. Claims 23-27 and 39 are rejected under 35 U.S.C. 112, first paragraph. Claim 23 recites a first direction of contraction extending along at least one axis of the wound. Claim 39 recites a first direction of anisotropic packing that extends parallel to at least one axis of the wound. The specification, while being enabling for a first direction of wound packing or first direction of contraction of wound packing that extends parallel to one axis of the wound, does not reasonably provide enablement for a first direction of packing or direction of contraction of packing that extends parallel to more than one axis of the wound, which is encompassed by the recited limitation "at least one axis". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. Applicant's Figure 3 clearly sets forth axes 56 and 57 of the wound that are generally parallel to the skin surface of the patient. It is clear that applicant uses the mathematical definition of axis as an imaginary line that is orthogonal to another line also defining an axis and therefore a single first direction, of packing or of contraction of packing, cannot be parallel to or extend along more than one of these axes simultaneously. Claims 24-27 are also rejected because they depend from claim 23.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 23, 27, 28 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Svedman (U.S. Patent No. 5,358,494).

With respect to **claim 23**: Svedman teaches a medical device for treating a wound of a patient, the wound having at least one axis extending generally parallel to the skin of the patient contiguous with the wound.

With regard to (a), the device comprises suction means arranged for applying continuous suction to the wound in the form of a syringe 12, inasmuch as Svedman discloses that the syringe is used to drain the wound and any interval of suction application is continuous in and of itself. With regard to the limitation "suction means for applying suction to the wound" applicant has disclosed a wall suction device or portable suction pump for applying suction interpreted herein as the means for applying suction. Svedman teaches a portable suction pump in the form of syringe 12. (Col. 3, lines 35-39)

With regard to (b), Svedman teaches an enclosure formed by flexible plate 1. The enclosure of Svedman is coupled to said source of suction 12 and engages the skin around the wound via adhesive layer 3, thus necessarily being arranged for maintaining continuous suction on the wound by engaging the skin of the patient around the wound. (Fig. 1, Col. 2, lines 34-38)

With regard to (c), Svedman teaches an anisotropic wound packing means in the form of a flexible pad 11 arranged for placement in the wound. Pad 11 comprises a cylindrical piece of synthetic fabric which is considered herein to be anisotropic as that term is understood from the disclosure, i.e. degree of contraction along each different dimensions of the structure is unequal to the others. (Col. 2, lines 56-58) Examiner's position is based upon Svedman's disclosure of a cylinder of fabric or foam. When suction is applied to such a cylinder, or any contractible material such as the fabric or foam of Svedman, the contraction is inherently and necessarily anisotropic because the same suction force is distributed to a far greater area in a cylinder along the direction of flow than the area perpendicular to the direction of flow that the force

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distributes to as a result of a cylinder's geometry. With regard to the limitation "inherently more contractible", in light of the lack of support for the term "inherently contractible", the claim is given its broadest reasonable interpretation. Wound packing 11 of Svedman has a first direction of contraction and a second direction of contraction due to its anisotropy and is thus inherently more contractible in said first direction, the direction perpendicular to flow, than the second direction, the direction parallel to flow. The wound packing is arranged to be placed in the wound with the first direction inherently and necessarily extending along at least one axis. The first direction of contraction of the foam or fabric pad of Svedman will necessarily extend along the at least one axis of the wound parallel to the skin adjacent the wound because Svedman discloses that the pad may take up more or less of the space in the wound cavity. ('494, Col. 2, lines 60, 61) When the pad 11 takes up more of the space, oriented either vertically or horizontally, the first direction of contraction will necessarily extend along said at least one axis of the wound, because whether the pad is oriented vertically in the wound cavity or horizontally, one of the directions of contraction upon application of suction has to be the first direction of contraction as claimed and that direction will always extend generally parallel to the skin surface, i.e. along said at least one axis of the wound. With regard to the limitation "to facilitate continuous contraction of the wound when continuous suction is applied to the wound", Svedman meets the limitations regarding application of continuous suction to an anisotropic wound packing, thus the wound packing of Svedman is fully functional to facilitate continuous contraction of the wound when continuous suction is applied to the wound.

With respect to **claim 27**: The phrase "generally spirally wound" is not clearly and explicitly defined in the disclosure by applicant. Thus the claim is given its broadest reasonable interpretation. The generally cylindrical gauze roll suggested by Svedman is considered herein

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to be generally spirally wound inasmuch as it is formed by winding the fabric at least once to form the cylinder. Thus, the device of Svedman renders the limitation "said packing comprises at least one generally spirally wound gauze roll" obvious.

With respect to **claim 28**: Applicant has not clearly and explicitly defined the phrase "substantially air-tight seal" which examiner interprets as differing from the air-tight seal of the embodiment depicted in applicant's Figs. 7 and 8. Therefore, the claim is given its broadest reasonable interpretation. The enclosure 1 disclosed by Svedman is considered herein to be arranged to create a substantially air-tight seal with the skin of the patient via adhesive and the application of suction to the plate and the space under the plate adjacent the wound. (Col. 2, lines 38-40, Col. 3, lines 35-44)

With respect to **claim 39**: Svedman teaches a method of controlling the direction of contraction of a wound of a patient, the wound having at least one axis extending generally parallel to the skin of the patient contiguous with the wound. With regard to (a) the method comprises the step of providing an anisotropic wound packing in the form of cylindrical piece of foam material 11 having a first direction of contraction perpendicular to suction flow when suction is applied that renders the packing anisotropic and a second direction of contraction. Examiner's position is based upon the definition of the term "anisotropic" as understood from applicant's disclosure, specifically that it is the suction flow that renders the packing anisotropic, not the packing itself. With regard to the limitation "inherently more contractible", in light of the lack of support for the term "inherently contractible", the claim is given its broadest reasonable interpretation. Wound packing 11 of Svedman has a first direction of contraction and a second direction of contraction

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due to its anisotropy and is thus inherently more contractible in said first direction, the direction perpendicular to suction flow, than the second direction, the direction parallel to suction flow.

With regard to (b), the method comprises the step of placing said anisotropic wound packing in the form of a pad 11 arranged for placement in the wound. Pad 11 comprises a cylindrical piece of synthetic fabric which is considered herein to be anisotropic as it is considerably more difficult to contract a roll of fabric via suction in directions that are orthogonal to the direction of suction flow (Col. 2, lines 56-58) in said wound in a predetermined orientation wherein said first direction of said anisotropic wound packing necessarily extends parallel to said at least one axis of the wound because Svedman discloses that the pad may take up more or less of the space in the wound cavity. (Col. 2, lines 60, 61) When the pad 11 takes up more of the space, oriented either vertically or horizontally, the first direction of contraction will necessarily extend along said at least one axis of the wound, because whether the pad is oriented vertically in the wound cavity or horizontally, one of the directions of contraction upon application of suction has to be the first direction of contraction as claimed and that direction will always extend generally parallel to the skin surface, i.e. along said at least one axis of the wound. With regard to the limitation "to allow a controlled strain to be imposed on the wound tissue along said at least one axis", since the method of Svedman anticipates the step of placing an anisotropic wound packing wherein a first direction of the wound packing extends parallel to at least one axis of the wound, the method as practiced will necessarily allow a controlled strain to be imposed on the wound tissue along said at least one axis.

With regard to (c), the method disclosed by Svedman comprises the step of sealing said wound with said wound packing and a flexible plate 1 to produce an enclosed space contiguous with the wound. (Fig. 1, Col. 2, lines 34-38)

With regard to (d), Svedman teaches applying suction to the enclosed space and said wound by suction means 12 and maintaining suction therein (Fig. 1, Col. 3, lines 35-44) whereupon contraction along said wound axis is encouraged necessarily as a resulting of executing the step of application of suction to the wound and the anisotropic packing.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 24-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Svedman (U.S. Patent No. 5,358,494).

With respect to **claim 24**: Svedman teaches that the wound packing comprises a cylindrical piece of synthetic fabric. Svedman does not explicitly teach gauze. However, it is well known in the art to roll up gauze into a cylindrical configuration and place it in a wound to absorb wound

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exudate. Therefore, it would be obvious to modify the device of Svedman such that the cylindrical piece of synthetic fabric is a roll of gauze with a reasonable expectation of success to facilitate healing of a wound by absorbing wound exudate.

With respect to **claim 25**: The wound packing fairly suggested by Svedman comprises at least one generally cylindrical gauze roll necessarily having a generally longitudinal axis and radial axes. The radial axis extends generally parallel to said first direction of contraction, inasmuch as contraction occurs in the longitudinal and radial directions regardless of the position in which the roll is oriented within the wound and regardless of the direction of suction flow. The motivation to modify the device of Svedman such that the wound packing is a cylindrical piece of gauze is stated *supra* with respect to claim 24.

With respect to **claim 26**: Svedman does not explicitly teach that the wound packing comprises a plurality of said cylindrical gauze rolls to be disposed with their respective longitudinal axes generally parallel to each other in the wound. However, a plurality of rolls would accomplish the same result as one roll, i.e. absorbing wound exudate. It would be obvious to one of ordinary skill in the art to modify the device of Svedman such that the packing 11 comprises a plurality of identical gauze rolls identical to the first roll suggested by Svedman with a reasonable expectation of success to provide an effective means of packing a wound. It has been held that the mere duplication of the essential working parts of a device involves only routine skill in the art. *St Regis paper Co. v. Bemis. Co.* 193 USPQ 8 (7th Cir. 1977) Thus the device suggested by Svedman renders the limitation "to be disposed with their respective longitudinal axes generally parallel to each other in the wound" obvious.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE J. HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Examiner, Art Unit 3761